

PCT ENT COOPERATION TREA

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NOTIFICATION OF ELECTION

(PCT Rule 61.2)

From the INTERNATIONAL BUREAU

To:

Assistant Commissioner for Patents
United States Patent and Trademark
Office
Box PCT
Washington, D.C.20231
ETATS-UNIS D'AMERIQUE

in its capacity as elected Office

Date of mailing (day/month/year) 17 October 2000 (17.10.00)	Applicant's or agent's file reference 03063-0491WP
International application No. PCT/US00/02498	Priority date (day/month/year) 03 February 1999 (03.02.99)
International filing date (day/month/year) 01 February 2000 (01.02.00)	
Applicant LAL, Renu, B. et al	

1. The designated Office is hereby notified of its election made:

☒ in the demand filed with the International Preliminary Examining Authority on:
01 September 2000 (01.09.00)

☐ in a notice effecting later election filed with the International Bureau on:

2. The election ☒ was
☐ was not

made before the expiration of 19 months from the priority date or, where Rule 32 applies, within the time limit under Rule 32.2(b).

The International Bureau of WIPO
34, chemin des Colombettes
1211 Geneva 20, Switzerland

Facsimile No.: (41-22) 740.14.35

Authorized officer

Dorothee Mülhausen

Telephone No.: (41-22) 338.83.38

PATENT COOPERATION TREATY

PCT

From the INTERNATIONAL BUREAU

NOTIFICATION OF THE RECORDING
OF A CHANGE(PCT Rule 92bis.1 and
Administrative Instructions, Section 422)

To:

MILLER, Mary, L.
Needle & Rosenberg, P.C.
Suite 1200
127 Peachtree Street, N.E.
Atlanta, GA 30303-1811
ETATS-UNIS D'AMERIQUE

Date of mailing (day/month/year) 08 March 2001 (08.03.01)	IMPORTANT NOTIFICATION
Applicant's or agent's file reference 14114.0346P1	
International application No. PCT/US00/02498	International filing date (day/month/year) 01 February 2000 (01.02.00)

1. The following indications appeared on record concerning:

☐ the applicant ☐ the inventor ☒ the agent ☐ the common representative

Name and Address MILLER, Mary, L. Needle & Rosenberg, P.C. 127 Peachtree Street, N.E. Atlanta, GA 30326 United States of America	State of Nationality	State of Residence
	Telephone No. (404) 688 0770	
	Facsimile No. (404) 688 9880	
	Teleprinter No.	

2. The International Bureau hereby notifies the applicant that the following change has been recorded concerning:

☐ the person ☐ the name ☒ the address ☐ the nationality ☐ the residence

Name and Address MILLER, Mary, L. Needle & Rosenberg, P.C. Suite 1200 127 Peachtree Street, N.E. Atlanta, GA 30303-1811 United States of America	State of Nationality	State of Residence
	Telephone No. (404) 688 0770	
	Facsimile No. (404) 688 9880	
	Teleprinter No.	

MLM/ISC/7mb
DOCKETED
By *[Signature]* Date 3/21/01
Reviewed _____
Name / Date _____

3. Further observations, if necessary:

4. A copy of this notification has been sent to:

<input checked="" type="checkbox"/> the receiving Office	<input type="checkbox"/> the designated Offices concerned
<input type="checkbox"/> the International Searching Authority	<input checked="" type="checkbox"/> the elected Offices concerned
<input checked="" type="checkbox"/> the International Preliminary Examining Authority	<input type="checkbox"/> other: _____

The International Bureau of WIPO
34, chemin des Colombettes
1211 Geneva 20, Switzerland

Authorized officer

[Signature]
Dorothee Mülhausen

Facsimile No.: (41-22) 740.14.35

Telephone No.: (41-22) 338.83.38

PCT

NOTIFICATION OF THE RECORDING OF A CHANGE

(PCT Rule 92bis.1 and
Administrative Instructions, Section 422)

From the INTERNATIONAL BUREAU

To:

GREENE, Jamie, L.
Kilpatrick Stockton LLP
2400 Monarch Tower
3424 Peachtree Road, N.E.
Atlanta, GA 30326
ETATS-UNIS D'AMERIQUE

Date of mailing (day/month/year) 17 October 2000 (17.10.00)	Applicant's or agent's file reference 03063-0491WP
International application No. PCT/US00/02498	International filing date (day/month/year) 01 February 2000 (01.02.00)

1. The following indications appeared on record concerning:

☐ the applicant
 ☐ the inventor
 ☒ the agent
 ☐ the common representative

Name and Address GREENE, Jamie, L. Jones & Askew, LLP 2400 Monarch Tower 3424 Peachtree Road, N.E. Atlanta, GA 30326 United States of America	State of Nationality	State of Residence
	Telephone No. (404) 949-2400	
	Facsimile No. (404) 949-2499	
	Teleprinter No.	

2. The International Bureau hereby notifies the applicant that the following change has been recorded concerning:

☐ the person
 ☒ the name
 ☐ the address
 ☐ the nationality
 ☐ the residence

Name and Address GREENE, Jamie, L. Kilpatrick Stockton LLP 2400 Monarch Tower 3424 Peachtree Road, N.E. Atlanta, GA 30326 United States of America	State of Nationality	State of Residence
	Telephone No. (404) 949-2400	
	Facsimile No. (404) 949-2499	
	Teleprinter No.	

3. Further observations, if necessary:
Change in name of company.

4. A copy of this notification has been sent to:

☒ the receiving Office
 ☐ the designated Offices concerned
☐ the International Searching Authority
 ☒ the elected Offices concerned
☒ the International Preliminary Examining Authority
 ☐ other:

The International Bureau of WIPO 34, chemin des Colombettes 1211 Geneva 20, Switzerland	Authorized officer Dorothee Mülhausen
Facsimile No.: (41-22) 740.14.35	Telephone No.: (41-22) 338.83.38

By *mm* Date *2/28/01*
 Reviewed *mmH 3/29/01*
 Name / Date

PATENT COOPERATION TREATY
RECEIVED
 PCT FEB 28 2001

From the INTERNATIONAL BUREAU

**NOTIFICATION OF THE RECORDING
 OF A CHANGE**

(PCT Rule 92bis.1 and
 Administrative Instructions, Section 422)

To:

MILLER, Mary, L.
 Needle & Rosenberg, P.C.
 127 Peachtree Street, N.E.
 Atlanta, GA 30326
 ETATS-UNIS D'AMERIQUE

Date of mailing (day/month/year) 20 February 2001 (20.02.01)	IMPORTANT NOTIFICATION
Applicant's or agent's file reference 14114.0346P1	
International application No. PCT/US00/02498	International filing date (day/month/year) 01 February 2000 (01.02.00)

1. The following indications appeared on record concerning:

☒ the applicant
 ☐ the inventor
 ☐ the agent
 ☐ the common representative

Name and Address THE GOVERNMENT OF THE UNITED STATES OF AMERICA as represented by THE SECRETARY, DEPARTMENT OF HEALTH AND HUMAN SERVICES Centers for Disease Control and Prevention Technology Transfer Office Executive Park Drive Building 4, Suite 1103, M/S E-67 Atlanta, GA 30329	State of Nationality US	State of Residence US
	Telephone No.	
	Facsimile No.	
	Teleprinter No.	

2. The International Bureau hereby notifies the applicant that the following change has been recorded concerning:

☐ the person
 ☒ the name
 ☐ the address
 ☐ the nationality
 ☐ the residence

Name and Address THE GOVERNMENT OF THE UNITED STATES OF AMERICA, as represented by THE SECRETARY OF THE DEPARTMENT OF HEALTH AND HUMAN SERVICES Centers for Disease Control and Prevention Technology Transfer Office Executive Park Drive Building 4, Suite 1103, M/S E-67 Atlanta, GA 30329	State of Nationality US	State of Residence US
	Telephone No.	
	Facsimile No.	
	Teleprinter No.	

3. Further observations, if necessary:
Please note the new agent in the address box above, as well as the new file reference No.

4. A copy of this notification has been sent to:

☒ the receiving Office
 ☐ the designated Offices concerned
☐ the International Searching Authority
 ☒ the elected Offices concerned
☒ the International Preliminary Examining Authority
 ☐ other:

The International Bureau of WIPO 34, chemin des Colombettes 1211 Geneva 20, Switzerland Facsimile No.: (41-22) 740.14.35	Authorized officer <i>J. Rüttimann</i> Dorothee Mülhausen Telephone No.: (41-22) 338.83.38
---	--

PATENT COOPERATION TREATY

PCT

NOTIFICATION OF THE RECORDING
OF A CHANGE(PCT Rule 92bis.1 and
Administrative Instructions, Section 422)

From the INTERNATIONAL BUREAU

To:

MILLER, Mary, L.
Needle & Rosenberg, P.C.
Suite 1200
127 Peachtree Street, N.E.
Atlanta, GA 30303-1811
ETATS-UNIS D'AMERIQUE

Date of mailing (day/month/year)

08 March 2001 (08.03.01)

Applicant's or agent's file reference

14114.0346P1

International application No.

PCT/US00/02498

IMPORTANT NOTIFICATION

International filing date (day/month/year)

01 February 2000 (01.02.00)

1. The following indications appeared on record concerning:

☒ the applicant ☐ the inventor ☐ the agent ☐ the common representative

Name and Address

THE GOVERNMENT OF THE UNITED
STATES OF AMERICA as represented
by THE SECRETARY, DEPARTMENT OF
HEALTH AND HUMAN SERVICES
Centers for Disease Control and Prevention
Technology Transfer Office
Executive Park Drive
Building 4, Suite 1103, M/S E-67
Atlanta, GA 30329

State of Nationality

US

State of Residence

US

Telephone No.

Facsimile No.

Teleprinter No.

2. The International Bureau hereby notifies the applicant that the following change has been recorded concerning:

☐ the person ☒ the name ☐ the address ☐ the nationality ☐ the residence

Name and Address

THE GOVERNMENT OF THE UNITED
STATES OF AMERICA, as represented
by THE SECRETARY OF THE DEPARTMENT
OF HEALTH AND HUMAN SERVICES
Centers for Disease Control and Prevention
Technology Transfer Office
Executive Park Drive
Building 4, Suite 1103, M/S E-67
Atlanta, GA 30329

State of Nationality

US

State of Residence

US

Telephone No.

Facsimile No.

Teleprinter No.

3. Further observations, if necessary:

Corrected version of form PCT/IB/306 dated 20 February 2001 (agent's address). Please note
the new agent in the address box above, as well as the new file reference number.

4. A copy of this notification has been sent to:

☒ the receiving Office ☐ the designated Offices concerned
☐ the International Searching Authority ☒ the elected Offices concerned
☒ the International Preliminary Examining Authority ☐ other:The International Bureau of WIPO
34, chemin des Colombettes
1211 Geneva 20, Switzerland

Authorized officer

Dorothee Mülhausen

Facsimile No.: (41-22) 740.14.35

Telephone No.: (41-22) 338.83.38

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PATENT COOPERATION TREATY

JUL 1 1 2001

NEEDLE & ROSENBERG PCT

From the INTERNATIONAL BUREAU

NOTIFICATION OF THE RECORDING
OF A CHANGE(PCT Rule 92bis.1 and
Administrative Instructions, Section 422)

To:

MILLER, Mary, L.
Needle & Rosenberg, P.C.
Suite 1200
127 Peachtree Street, N.E.
Atlanta, GA 30303-1811
ETATS-UNIS D'AMERIQUE

Date of mailing (day/month/year)

29 June 2001 (29.06.01)

Applicant's or agent's file reference

14114.0346P1

International application No.

PCT/US00/02498

IMPORTANT NOTIFICATION

International filing date (day/month/year)

01 February 2000 (01.02.00)

1. The following indications appeared on record concerning:



the applicant



the inventor



the agent



the common representative

Name and Address

THE GOVERNMENT OF THE UNITED
STATES OF AMERICA, as represented
by THE SECRETARY OF THE DEPARTMENT
OF HEALTH AND HUMAN SERVICES
Centers for Disease Control and Prevention
Technology Transfer Office
Executive Park Drive
Building 4, Suite 1103, M/S E-67
Atlanta, GA 30329

State of Nationality

US

State of Residence

US

Telephone No.

Facsimile No.

Teleprinter No.

2. The International Bureau hereby notifies the applicant that the following change has been recorded concerning:



the person



the name



the address



the nationality



the residence

Name and Address

THE GOVERNMENT OF THE UNITED
STATES OF AMERICA, as represented
by THE SECRETARY, DEPARTMENT
OF HEALTH AND HUMAN SERVICES
Centers for Disease Control and PREVENTION
Technology Transfer Office
1600 Clifton Road, N.E., MS E-67
Atlanta, GA 30333
United States of America

State of Nationality

US

State of Residence

US

Telephone No.

Facsimile No.

Teleprinter No.

By

Jmw

Date

7/11/01

3. Further observations, if necessary:

Reviewed

Name/Date

4. A copy of this notification has been sent to:



the receiving Office



the International Searching Authority



the International Preliminary Examining Authority



the designated Offices concerned



the elected Offices concerned



other:

The International Bureau of WIPO
34, chemin des Colombettes
1211 Geneva 20, Switzerland

Facsimile No.: (41-22) 740.14.35

Authorized officer

Dorothee Mülhausen

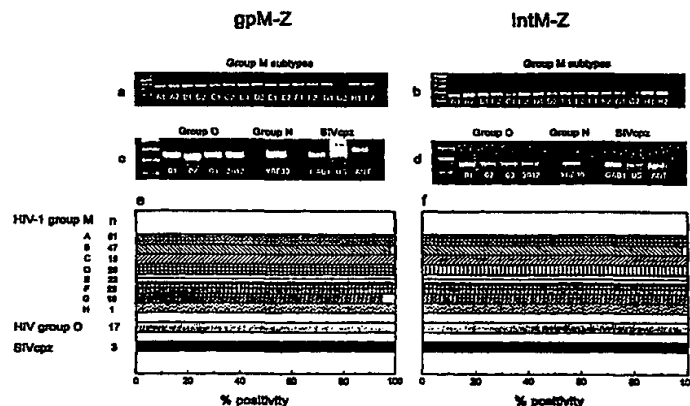
Telephone No.: (41-22) 338.83.38



INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(51) International Patent Classification ⁷ : C12Q 1/68		A2	(11) International Publication Number: WO 00/46403
			(43) International Publication Date: 10 August 2000 (10.08.00)
(21) International Application Number: PCT/US00/02498		(81) Designated States: AE, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, CA, CH, CN, CR, CU, CZ, DE, DK, DM, EE, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, NO, NZ, PL, PT, RO, RU, SD, SE, SG, SI, SK, SL, TJ, TM, TR, TT, TZ, UA, UG, US, UZ, VN, YU, ZA, ZW, ARIPO patent (GH, GM, KE, LS, MW, SD, SL, SZ, TZ, UG, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, GW, ML, MR, NE, SN, TD, TG).	
(22) International Filing Date: 1 February 2000 (01.02.00)			
(30) Priority Data: 60/118,357 3 February 1999 (03.02.99) US			
(71) Applicant (for all designated States except US): THE GOVERNMENT OF THE UNITED STATES OF AMERICA as represented by THE SECRETARY, DEPARTMENT OF HEALTH AND HUMAN SERVICES [US/US]; Centers for Disease Control and Prevention, Technology Transfer Office, Executive Park Drive, Building 4, Suite 1103, M/S E-67, Atlanta, GA 30329 (US).		Published Without international search report and to be republished upon receipt of that report.	
(72) Inventors; and (75) Inventors/Applicants (for US only): LAL, Renu, B. [IN/US]; 2070 Asgard Court, Atlanta, GA 30345 (US). PIENIAZEK, Danuta [US/US]; 420 Hunt River Way, Suwanee, GA 30024 (US). YANG, Chunfu [CN/US]; 440 Rams Way, Tucker, GA 30084 (US).			
(74) Agents: GREENE, Jamie, L. et al.; Jones & Askew, LLP, 2400 Monarch Tower, 3424 Peachtree Road, N.E., Atlanta, GA 30326 (US).			

(54) Title: METHODS AND REAGENTS FOR MOLECULAR DETECTION OF HIV-1 GROUPS M, N AND O



(57) Abstract

Reagents and assays for detecting HIV-1 groups M and O and optionally HIV-1 group N and SIVcpz are provided. The reagents are nucleic acid primers for the hybridization to, amplification and subsequent detection of HIV-1 groups M, N and O and SIVcpz in a biological sample. The primers are oligonucleotides that selectively hybridize to the highly conserved regions of the *env* and *pol* regions of HIV-1. The assays employ the primers for HIV-1 nucleic acid amplification using amplification techniques such as reverse transcription and the polymerase chain reaction. The assays are useful for diagnosing an HIV-1 group M, HIV-1 group N, or an HIV-1 group O infection in a patient. Due to the high sensitivity of the assays, small concentrations of HIV in a biological sample can be detected, thereby allowing diagnosis at an early stage of infection. The assays are also useful for detecting HIV-1 contamination in a biological fluid such as blood. The assays are qualitative or quantitative and are therefore useful for viral load determinations of HIV-1 groups M, N or O in a patient undergoing treatment for HIV-1 infection. Viral load determinations can be used to monitor the progress of the treatment regimen or the development of drug resistance and can be used to predict disease progression.

FOR THE PURPOSES OF INFORMATION ONLY

Codes used to identify States party to the PCT on the front pages of pamphlets publishing international applications under the PCT.

AL	Albania	ES	Spain	LS	Lesotho	SI	Slovenia
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PATENT COOPERATION TREATY

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APR 11 2001

NR

From the
INTERNATIONAL PRELIMINARY EXAMINING AUTHORITY

To:

GREENE, Jamie L.
Kilpatrick's Stockton, LLP
2400 Monarch Tower
3424 Peachtree Road, N.E.
Atlanta, GA 30326
ETATS-UNIS D'AMERIQUE

MAR 27 2001

SCANNED

NEEDLE & ROSENBERG PCT
NEEDLE & ROSENBERGNOTIFICATION OF TRANSMITTAL OF
THE INTERNATIONAL PRELIMINARY
EXAMINATION REPORT

(PCT Rule 71.1)

Date of mailing
(day/month/year)

19.03.2001

Applicant's or agent's file reference

03063-0491WP

14114.0346P1

IMPORTANT NOTIFICATION

International application No.
PCT/US00/02498International filing date (day/month/year)
01/02/2000Priority date (day/month/year)
03/02/1999

Applicant

THE GOVERNMENT OF THE UNITED STATES OF AMERICA as

1. The applicant is hereby notified that this International Preliminary Examining Authority transmits herewith the international preliminary examination report and its annexes, if any, established on the international application.
2. A copy of the report and its annexes, if any, is being transmitted to the International Bureau for communication to all the elected Offices.

3. Where required by any of the elected Offices, the International Bureau will prepare an English translation of the report (but not of any annexes) and will transmit such translation to those Offices.

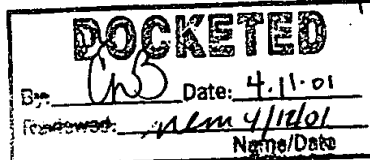
4. REMINDER

The applicant must enter the national phase before each elected Office by performing certain acts (filing translations and paying national fees) within 30 months from the priority date (or later in some Offices) (Article 39(1)) (see also the reminder sent by the International Bureau with Form PCT/IB/301).

Where a translation of the international application must be furnished to an elected Office, that translation must contain a translation of any annexes to the international preliminary examination report. It is the applicant's responsibility to prepare and furnish such translation directly to each elected Office concerned.

For further details on the applicable time limits and requirements of the elected Offices, see Volume II of the PCT Applicant's Guide.

MLM/STC



Name and mailing address of the IPEA/

European Patent Office
D-80298 Munich
Tel. +49 89 2399 - 0 Tx: 523656 epmu d
Fax: +49 89 2399 - 4465

Authorized officer

Pedersen, C


Tel. +49 89 2399-8063 8161



PCT

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference 03063-0491WP		FOR FURTHER ACTION	See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416)
International application No. PCT/US00/02498	International filing date (day/month/year) 01/02/2000	Priority date (day/month/year) 03/02/1999	
International Patent Classification (IPC) or national classification and IPC C12Q1/68			
Applicant THE GOVERNMENT OF THE UNITED STATES OF AMERICA as			
<p>1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.</p> <p>2. This REPORT consists of a total of 6 sheets, including this cover sheet.</p> <p><input type="checkbox"/> This report is also accompanied by ANNEXES, i.e. sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).</p> <p>These annexes consist of a total of sheets.</p>			
<p>3. This report contains indications relating to the following items:</p> <ul style="list-style-type: none"> I <input checked="" type="checkbox"/> Basis of the report II <input type="checkbox"/> Priority III <input type="checkbox"/> Non-establishment of opinion with regard to novelty, inventive step and industrial applicability IV <input type="checkbox"/> Lack of unity of invention V <input checked="" type="checkbox"/> Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement VI <input type="checkbox"/> Certain documents cited VII <input checked="" type="checkbox"/> Certain defects in the international application VIII <input type="checkbox"/> Certain observations on the international application 			
Date of submission of the demand 01/09/2000		Date of completion of this report 19.03.2001	
Name and mailing address of the international preliminary examining authority:  European Patent Office D-80298 Munich Tel. +49 89 2399 - 0 Tx: 523656 epmu d Fax: +49 89 2399 - 4465		Authorized officer BROCHADO GARGANTA, M Telephone No. +49 89 2399 8935	



**INTERNATIONAL PRELIMINARY
EXAMINATION REPORT**

International application No. PCT/US00/02498

I. Basis of the report

1. This report has been drawn on the basis of (*substitute sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to the report since they do not contain amendments (Rules 70.16 and 70.17).):*)

Description, pages:

1-39 as originally filed

Claims, No.:

1-19 as originally filed

Drawings, sheets:

1/2-2/2 as originally filed

Sequence listing part of the description, pages:

1-5, filed with the letter of 23.05.00

2. With regard to the **language**, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.

These elements were available or furnished to this Authority in the following language: , which is:

- ☐ the language of a translation furnished for the purposes of the international search (under Rule 23.1(b)).
- ☐ the language of publication of the international application (under Rule 48.3(b)).
- ☐ the language of a translation furnished for the purposes of international preliminary examination (under Rule 55.2 and/or 55.3).

3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

- ☒ contained in the international application in written form.
- ☐ filed together with the international application in computer readable form.
- ☐ furnished subsequently to this Authority in written form.
- ☒ furnished subsequently to this Authority in computer readable form.
- ☒ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.
- ☒ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. The amendments have resulted in the cancellation of:

**INTERNATIONAL PRELIMINARY
EXAMINATION REPORT**

International application No. PCT/US00/02498

- ☐ the description, pages:
☐ the claims, Nos.:
☐ the drawings, sheets:

5. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed (Rule 70.2(c)):

(Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.)

6. Additional observations, if necessary:

V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Yes:	Claims	3,12
	No:	Claims	1-2, 4-11, 13-19
Inventive step (IS)	Yes:	Claims	
	No:	Claims	1-19
Industrial applicability (IA)	Yes:	Claims	1-19
	No:	Claims	

- 2. Citations and explanations**
see separate sheet

VII. Certain defects in the international application

The following defects in the form or contents of the international application have been noted:
see separate sheet

**INTERNATIONAL PRELIMINARY
EXAMINATION REPORT - SEPARATE SHEET**

International application No. PCT/US00/02498

Re Item V

Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Reference is made to the following documents:

(A) Human retroviruses and AIDS 1998: A compilation and analysis of nucleic acid and amino acid sequences', Korber, Kuiken, Foley, Hahn, Mccutchan, Mellors and Sodrosky, Los Alamos National Laboratory. D. Pieniazek et al.: Phylogenetic Analysis, III-112- III-117, Dec. 1998

(B) EP-A-0 617 132

2. The following intermediate documents cited in the Search Report:

(C) Yang et al.: Journal of Clinical Microbiology (1999 Aug), 37 (8) 2581-6

(D) Gao Feng et al.: Nature, vol. 397, no. 6718, 4 February 1999, pages 436-441

are considered to belong to the state of the art, as the date of priority is not validly claimed for all the claims of the present application.

For example, several nucleotide positions and SEQ ID NO were not indicated in the priority document:

- the nucleotide positions 4550, 4596, 4625, 4626, 4724, 4753, 4754, 4956, 4984, 4985, 5051, 5080 and 5126 (see claims 1, 3, 6, 8, 10, 12 and 18)

- the nucleotide positions 7789 to 7816, 8347 to 8374, 7850 to 7879, 8265 to 8294 and 8281 to 8310 (claims 2, 7 and 11)

- SEQ ID NO: 6, SEQ ID NO: 7, SEQ ID NO: 8 and SEQ ID NO: 9 (claims 5, 9, 13, 14, 16, 17 and 19).

**INTERNATIONAL PRELIMINARY
EXAMINATION REPORT - SEPARATE SHEET**

International application No. PCT/US00/02498

3. Novelty

- 3.1 The subject-matter of claim 1, referring to a nucleic acid primer, is not new in the sense of Article 33(2) PCT, because this matter is already known from document A.

Document A discloses the phylogenetic analysis of gp41 envelope of HIV-1 groups M, N and O strains, wherein a nucleic acid primer is used, which selectively hybridises to a highly conserved region of a nucleic acid molecule of HIV-1 between the nucleotide positions 7789 and 7816 of the HXB2 strain (see title and table 1).

Document C is also novelty destroying for the subject-matter of claim 1, according to the requirements of Article 33(2) PCT. Document C discloses the detection of phylogenetically diverse human immunodeficiency virus type 1 groups M and O from plasma by using highly sensitive and generic primers, wherein nucleic primers are indicated that hybridise between nucleotides 7789 and 7816, 8347 and 8374, 7850 and 7879 of the HBX2 strain (see title and page 2582, column 1).

- 3.2 The additional features of claims 2, 4 and 5 are also disclosed in documents A (see respectively, page III-113, lines 5 and 6; table 1; table 1) and C (see page 2582, column 1). Therefore these claims are not new (Article 33(2) PCT).
- 3.3 Claim 6 refers to a method for detecting HIV-1 groups M, N and O and chimpanzee SIV in a biological sample. Such a method is already described in documents A (see title and page III-113) and C (see title and Material and Methods). Thus, claim 6 is not new (Article 33(2) PCT).
- 3.4 The additional features of claims 7-11 and 13-16 are not novel (Article 33(2) PCT) as they are known from documents A (see page III-113) and C (see Material and Methods).
- 3.5 Claim 17 relates to a method for detecting HIV-1 group 1 N or chimpanzee SIV in a biological sample. Such a method is not new (Article 33(2) PCT), as it is already disclosed in documents A and C (see respectively, page III-113 and Material and Methods).

**INTERNATIONAL PRELIMINARY
EXAMINATION REPORT - SEPARATE SHEET**

International application No. PCT/US00/02498

- 3.6 Dependent claims 18 and 19 are also not new according to Article 33(2) PCT, because their additional features are known from these documents (see document A, page III-113 and document C, Material and Methods).
- 3.7 Document B refers to the same subject-matter of claims 1, 6 or 17, with the difference that the nucleotide positions of the present application are not indicated. Thus, this disclosure is not novelty destroying for the features of these claims (Article 33(2) PCT).
4. Inventive step
- 4.1 Claims 3 and 12 do not contain any additional features which in combination with the features of the claim on which they depend, meet the requirements of the PCT in respect of inventive step (Article 33(3) PCT).

The additional features of these claims relate to the hybridisation of the nucleotides to the region of the *pol* gene of HIV-1. Some positions within this gene are already indicated in document B (see abstract: positions 4804-4832), which refers to oligonucleotides and to a method similar to that of the present application. The skilled person would obviously be aware of the possibility of choosing oligonucleotides that could not only hybridise to the region of the *env* gene but also to the region of the *pol* gene referred in document B. Thus, claims 3 and 12 are not based on an inventive concept (Article 33(3) PCT).

Re Item VII

Certain defects in the international application

1. Contrary to the requirements of Rule 5.1(a)(ii) PCT, the relevant background art disclosed in the documents A and B is not mentioned in the description, nor are these documents identified therein.

From the INTERNATIONAL SEARCHING AUTHORITY

PCT

To:

JONES & ASKEW, LLP
Attn. GREENE, Jamie L.
2400 Monarch Tower
3424 Peachtree Road, N.E.
Atlanta, GA 30326
UNITED STATES OF AMERICA

RECEIVED

OCT 10 2000

SCANNED

NOTIFICATION OF TRANSMITTAL OF
THE INTERNATIONAL SEARCH REPORT
OR THE DECLARATION

(PCT Rule 44.1)

Applicant's or agent's file reference 03063-0491WP		Date of mailing (day/month/year) 06/10/2000
International application No. PCT/US 00/ 02498		International filing date (day/month/year) 01/02/2000
Applicant THE GOVERNMENT OF THE UNITED STATES OF AMERICA as		

1. ☒ The applicant is hereby notified that the International Search Report has been established and is transmitted herewith.

Filing of amendments and statement under Article 19:

The applicant is entitled, if he so wishes, to amend the claims of the International Application (see Rule 46):

When? The time limit for filing such amendments is normally 2 months from the date of transmittal of the International Search Report; however, for more details, see the notes on the accompanying sheet.

Where? Directly to the International Bureau of WIPO
34, chemin des Colombettes
1211 Geneva 20, Switzerland
Facsimile No.: (41-22) 740.14.35

For more detailed instructions, see the notes on the accompanying sheet.

2. ☐ The applicant is hereby notified that no International Search Report will be established and that the declaration under Article 17(2)(a) to that effect is transmitted herewith.

3. ☐ With regard to the protest against payment of (an) additional fee(s) under Rule 40.2, the applicant is notified that:

☐ the protest together with the decision thereon has been transmitted to the International Bureau together with the applicant's request to forward the texts of both the protest and the decision thereon to the designated Offices.


☐ no decision has been made yet on the protest; the applicant will be notified as soon as a decision is made.

4. **Further action(s):** The applicant is reminded of the following:

Shortly after 18 months from the priority date, the international application will be published by the International Bureau. If the applicant wishes to avoid or postpone publication, a notice of withdrawal of the international application, or of the priority claim, must reach the International Bureau as provided in Rules 90bis.1 and 90bis.3, respectively, before the completion of the technical preparations for international publication.

Within 19 months from the priority date, a demand for international preliminary examination must be filed if the applicant wishes to postpone the entry into the national phase until 30 months from the priority date (in some Offices even later).

Within 20 months from the priority date, the applicant must perform the prescribed acts for entry into the national phase before all designated Offices which have not been elected in the demand or in a later election within 19 months from the priority date or could not be elected because they are not bound by Chapter II.

Name and mailing address of the International Searching Authority  European Patent Office, P.B. 5818 Patentlaan 2 NL-2280 HV Rijswijk Tel. (+31-70) 340-2040, Tx. 31 651 epo nl, Fax: (+31-70) 340-3016	Authorized officer Catherine Humbert
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These Notes are intended to give the basic instructions concerning the filing of amendments under article 19. The Notes are based on the requirements of the Patent Cooperation Treaty, the Regulations and the Administrative Instructions under that Treaty. In case of discrepancy between these Notes and those requirements, the latter are applicable. For more detailed information, see also the PCT Applicant's Guide, a publication of WIPO.

In these Notes, "Article", "Rule", and "Section" refer to the provisions of the PCT, the PCT Regulations and the PCT Administrative Instructions respectively.

INSTRUCTIONS CONCERNING AMENDMENTS UNDER ARTICLE 19

The applicant has, after having received the international search report, one opportunity to amend the claims of the international application. It should however be emphasized that, since all parts of the international application (claims, description and drawings) may be amended during the international preliminary examination procedure, there is usually no need to file amendments of the claims under Article 19 except where, e.g. the applicant wants the latter to be published for the purposes of provisional protection or has another reason for amending the claims before international publication. Furthermore, it should be emphasized that provisional protection is available in some States only.

What parts of the international application may be amended?

Under Article 19, only the claims may be amended.

During the international phase, the claims may also be amended (or further amended) under Article 34 before the International Preliminary Examining Authority. The description and drawings may only be amended under Article 34 before the International Examining Authority.

Upon entry into the national phase, all parts of the international application may be amended under Article 28 or, where applicable, Article 41.

When?

Within 2 months from the date of transmittal of the international search report or 16 months from the priority date, whichever time limit expires later. It should be noted, however, that the amendments will be considered as having been received on time if they are received by the International Bureau after the expiration of the applicable time limit but before the completion of the technical preparations for international publication (Rule 46.1).

Where not to file the amendments?

The amendments may only be filed with the International Bureau and not with the receiving Office or the International Searching Authority (Rule 46.2).

Where a demand for international preliminary examination has been/is filed, see below.

How?

Either by cancelling one or more entire claims, by adding one or more new claims or by amending the text of one or more of the claims as filed.

A replacement sheet must be submitted for each sheet of the claims which, on account of an amendment or amendments, differs from the sheet originally filed.

All the claims appearing on a replacement sheet must be numbered in Arabic numerals. Where a claim is cancelled, no renumbering of the other claims is required. In all cases where claims are renumbered, they must be renumbered consecutively (Administrative Instructions, Section 205(b)).

The amendments must be made in the language in which the international application is to be published.

What documents must/may accompany the amendments?

Letter (Section 205(b)):

The amendments must be submitted with a letter.

The letter will not be published with the international application and the amended claims. It should not be confused with the "Statement under Article 19(1)" (see below, under "Statement under Article 19(1)").

The letter must be in English or French, at the choice of the applicant. However, if the language of the international application is English, the letter must be in English; if the language of the international application is French, the letter must be in French.

The letter must indicate the differences between the claims as filed and the claims as amended. It must, in particular, indicate, in connection with each claim appearing in the international application (it being understood that identical indications concerning several claims may be grouped), whether

- (i) the claim is unchanged;
- (ii) the claim is cancelled;
- (iii) the claim is new;
- (iv) the claim replaces one or more claims as filed;
- (v) the claim is the result of the division of a claim as filed.

The following examples illustrate the manner in which amendments must be explained in the accompanying letter:

1. [Where originally there were 48 claims and after amendment of some claims there are 51]:
"Claims 1 to 29, 31, 32, 34, 35, 37 to 48 replaced by amended claims bearing the same numbers; claims 30, 33 and 36 unchanged; new claims 49 to 51 added."
2. [Where originally there were 15 claims and after amendment of all claims there are 11]:
"Claims 1 to 15 replaced by amended claims 1 to 11."
3. [Where originally there were 14 claims and the amendments consist in cancelling some claims and in adding new claims]:
"Claims 1 to 6 and 14 unchanged; claims 7 to 13 cancelled; new claims 15, 16 and 17 added." or
"Claims 7 to 13 cancelled; new claims 15, 16 and 17 added; all other claims unchanged."
4. [Where various kinds of amendments are made]:
"Claims 1-10 unchanged; claims 11 to 13, 18 and 19 cancelled; claims 14, 15 and 16 replaced by amended claim 14; claim 17 subdivided into amended claims 15, 16 and 17; new claims 20 and 21 added."

"Statement under article 19(1)" (Rule 46.4)

The amendments may be accompanied by a statement explaining the amendments and indicating any impact that such amendments might have on the description and the drawings (which cannot be amended under Article 19(1)).

The statement will be published with the international application and the amended claims.

It must be in the language in which the international application is to be published.

It must be brief, not exceeding 500 words if in English or if translated into English.

It should not be confused with and does not replace the letter indicating the differences between the claims as filed and as amended. It must be filed on a separate sheet and must be identified as such by a heading, preferably by using the words "Statement under Article 19(1)."

It may not contain any disparaging comments on the international search report or the relevance of citations contained in that report. Reference to citations, relevant to a given claim, contained in the international search report may be made only in connection with an amendment of that claim.

Consequence if a demand for international preliminary examination has already been filed

If, at the time of filing any amendments under Article 19, a demand for international preliminary examination has already been submitted, the applicant must preferably, at the same time of filing the amendments with the International Bureau, also file a copy of such amendments with the International Preliminary Examining Authority (see Rule 62.2(a), first sentence).

Consequence with regard to translation of the international application for entry into the national phase

The applicant's attention is drawn to the fact that, where upon entry into the national phase, a translation of the claims as amended under Article 19 may have to be furnished to the designated/elected Offices, instead of, or in addition to, the translation of the claims as filed.

For further details on the requirements of each designated/elected Office, see Volume II of the PCT Applicant's Guide.

PCT

INTERNATIONAL SEARCH REPORT

(PCT Article 18 and Rules 43 and 44)

Applicant's or agent's file reference 03063-0491WP	FOR FURTHER ACTION see Notification of Transmittal of International Search Report (Form PCT/ISA/220) as well as, where applicable, item 5 below.	
International application No. PCT/US 00/ 02498	International filing date (day/month/year) 01/02/2000	(Earliest) Priority Date (day/month/year) 03/02/1999
Applicant THE GOVERNMENT OF THE UNITED STATES OF AMERICA as		

This International Search Report has been prepared by this International Searching Authority and is transmitted to the applicant according to Article 18. A copy is being transmitted to the International Bureau.

This International Search Report consists of a total of 4 sheets.

☒ It is also accompanied by a copy of each prior art document cited in this report.

1. Basis of the report

a. With regard to the **language**, the international search was carried out on the basis of the international application in the language in which it was filed, unless otherwise indicated under this item.

☐ the international search was carried out on the basis of a translation of the international application furnished to this Authority (Rule 23.1(b)).

b. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international search was carried out on the basis of the sequence listing:

☒ contained in the international application in written form.

☐ filed together with the international application in computer readable form.

☐ furnished subsequently to this Authority in written form.

☒ furnished subsequently to this Authority in computer readable form.

☒ the statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.

☒ the statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished

2. ☐ **Certain claims were found unsearchable** (See Box I).

3. ☐ **Unity of invention is lacking** (see Box II).

4. With regard to the **title**,

☒ the text is approved as submitted by the applicant.

☐ the text has been established by this Authority to read as follows:

5. With regard to the **abstract**,

☒ the text is approved as submitted by the applicant.

☐ the text has been established, according to Rule 38.2(b), by this Authority as it appears in Box III. The applicant may, within one month from the date of mailing of this international search report, submit comments to this Authority.

6. The figure of the **drawings** to be published with the abstract is Figure No.

☐ as suggested by the applicant.

☐ because the applicant failed to suggest a figure.

☐ because this figure better characterizes the invention.

☒ None of the figures.

INTERNATIONAL SEARCH REPORT

International Application No.

P 00/02498

A. CLASSIFICATION OF SUBJECT MATTER

IPC 7 C12Q1/70

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC 7 C12Q

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

EPO-Internal, WPI Data, PAJ, STRAND, MEDLINE, BIOSIS, CHEM ABS Data

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	<p>"Human retroviruses and AIDS 1998: A compilation and analysis of nucleic acid and amino acid sequences" 'Online! 1998, KORBER, KUIKEN, FOLEY, HAHN, MCCUTCHAN, MELLORS, AND SODROSKI (EDS.) LOS ALAMOS NATIONAL LABORATORY, LOS ALAMOS, NEW MEXICO XP002147694 Retrieved from the Internet: <URL: http://hiv-web.lanl.gov/> 'retrieved on 2000-09-15! PIENIAZEK ET AL: "Phylogenetic Analysis of gp 41 envelope of HIV-1 groups M,N, and O sterains provides an alternate region for subtype determination." (1998 DEC) III-112 -III-117 the whole document</p> <p style="text-align: center;">---</p> <p style="text-align: center;">-/--</p>	1,2, 4-11, 13-16

☒ Further documents are listed in the continuation of box C.☒ Patent family members are listed in annex.

* Special categories of cited documents :

- *A* document defining the general state of the art which is not considered to be of particular relevance
- *E* earlier document but published on or after the international filing date
- *L* document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
- *O* document referring to an oral disclosure, use, exhibition or other means
- *P* document published prior to the international filing date but later than the priority date claimed

T later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

X document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

Y document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

G document member of the same patent family

Date of the actual completion of the international search

18 September 2000

Date of mailing of the international search report

06/10/2000

Name and mailing address of the ISA

European Patent Office, P.B. 5818 Patentlaan 2
NL - 2280 HV Rijswijk
Tel. (+31-70) 340-2040, Tx. 31 651 epo nl,
Fax: (+31-70) 340-3016

Authorized officer

Reuter, U

International Application No.

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

—/—

INTERNATIONAL SEARCH REPORT

International Application No

US 00/02498

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	<p>SIMON FRANCOIS ET AL: "Identification of a new human immunodeficiency virus type 1 distinct from group M and group O." NATURE MEDICINE, vol. 4, no. 9, 1998, pages 1032-1037, XP002147690 ISSN: 1078-8956 cited in the application the whole document</p> <p>---</p>	1-19
A	<p>VANDEN HAESVELDE MARLEEN M ET AL: "Sequence analysis of a highly divergent HIV-1 related lentivirus isolated from a wild captured chimpanzee." VIROLOGY, vol. 221, no. 2, 1996, pages 346-350, XP002147691 ISSN: 0042-6822 the whole document</p> <p>---</p>	1-19
A	<p>CLEWLEY, J. P. (1) ET AL: "A novel simian immunodeficiency virus (SIVdr1) pol sequence from the drill monkey, Mandrillus leucophaeus." JOURNAL OF VIROLOGY, (DEC., 1998) VOL. 72, NO. 12, PP. 10305-10309. , XP002923012 the whole document</p> <p>---</p>	1-19
P,X	<p>YANG C ET AL: "Detection of phylogenetically diverse human immunodeficiency virus type 1 groups M and O from plasma by using highly sensitive and specific generic primers." JOURNAL OF CLINICAL MICROBIOLOGY, (1999 AUG) 37 (8) 2581-6. , XP002147692 the whole document</p> <p>---</p>	1,2, 4-11, 13-16
P,A	<p>GAO FENG ET AL: "Origin of HIV-1 in the chimpanzee Pan troglodytes troglodytes." NATURE (LONDON), vol. 397, no. 6718, 4 February 1999 (1999-02-04), pages 436-441, XP002147693 ISSN: 0028-0836 cited in the application the whole document</p> <p>-----</p>	1-19

INTERNATIONAL SEARCH REPORT

Information on patent family members

International Application No

US 00/02498

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			FR 2652091 A	22-03-1991
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			CA 1339733 A	17-03-1998
			DE 3854313 D	21-09-1995
			JP 1091786 A	11-04-1989
			US 5604114 A	18-02-1997
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INTERNATIONAL SEARCH REPORT

Information on patent family members

International Application No

US 00/02498

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WO 9707808 A	06-03-1997	AU 702266 B AU 6770696 A CA 2229749 A EP 0865282 A NZ 315890 A US 5958768 A	18-02-1999 19-03-1997 06-03-1997 23-09-1998 28-10-1998 28-09-1999